K040116

APR 2 0 2004

Exhibit #1

510(K) SUMMARY

This summary of 5l0(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA l990 and 21 CFR §807.92.

The assigned 5l0(k) number is:_____.

1. **Submitter's Identification:**

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1141-1, Baekseok-dong ,Ilsan-gu,
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PHONE : +82-31-909-8275
FAX: +82-31-909-8276

Date Summary Prepared: January 19, 2004

2. **Name of the Device:**

Trade/Proprietary Name:

Hawk Intraoral Camera and Accessories

Classification Name:

Dental Operative Unit and Accessories

Class in which Device has been placed:

The Dental devices panel has classified this device as Class I, 21 CFR Part 820.6640, Product Code EIA.

3. **Predicate Device Information:**

The Hawk Intraoral Camera and Accessories is substantially equivalent to the Veracan Intraoral camera and accessories distributed by Lumalite, Inc., K 021083.

4. **Device Description:**

Hawk Intraoral Camera composed of light (25g), small (185 x10mm) hand piece along with docking station.

The hand piece consists of a focusing mechanism to assist the doctor in taking video of the patient's mouth. The hand piece connects to docking station via cable. The docking station attaches directly to monitor, TV, or computer via standard composite connection. It uses high definition imaging (480 lines) to capture images at 78 degrees field of view. Hawk Intraoral Camera includes also footswitch.

5. **Intended Use:**

The Hawk Intraoral Camera and Accessories are indicated for use to provide a view of mouth to assist the dentist in describing dental procedures and to show the patient the mouth before and after dental procedures.

6. **Comparison to Predicate Device:**

The Hawk Intraoral Camera is substantially identical to the predicate in intended use, operation, safety and function.

7. **Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:**

Testing information demonstrating safety and effectiveness of the Hawk Intraoral Camera in the intended environment of use is supported by testing that was conducted in accordance with EN 60601-1, EN 60601-2, EN 61000-3-2 and EN 61000-3-3.

None of the testing demonstrated any design characteristics that violated the requirements of the standards or resulted in any safety hazards.

8. **Discussion of Clinical Tests Performed:**

Clinical testing was not conducted.

9. **Conclusions:**

The Hawk Intraoral Camera is substantially equivalent to the predicate and is safe and effective for it's intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 0 2004

DXM Company Limited
C/O Ms. Carolann Kotula
Official Correspondents
MDI Consultants, Incorporated
55 Northern Boulevard Suite 200
Great Neck, New York 11021

Re: K040116
Trade/Device Name: Hawk Intraoral Camera and Accessories
Regulation Number: 872.6640
Regulation Name: Dental Operative Unit and Accessories
Regulatory Class: I
Product Code: EIA
Dated: April 8, 2004
Received: April 9, 2004

Dear Ms. Kotula:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Exhibit B

Indications for Use

510(k) Number (if known): K040116

Device Name: Hawk Intraoral Camera

Indications For Use:

The Hawk Intraoral Camera and Accessories are indicated for use to provide a view of mouth to assist the dentist in describing dental procedures and to show the patient the mouth before and after dental procedures.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Robert S. Betz DDS for Dr. Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K040116